

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8519

Bartle, C.J.

August 10, 2010

Wanda Walker ("Ms. Walker" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Steven S. Gubin, M.D. Based on an echocardiogram dated February 19, 2002, Dr. Gubin attested in Part II of Ms. Walker's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II Benefits in the amount of \$528,405.<sup>3</sup>

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2. (...continued)  
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of  
(continued...)

In the report of claimant's echocardiogram, Dr. Gubin stated that claimant's ejection fraction was 55%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b)iv).

In January, 2004, the Trust forwarded the claim for review by Michael E. Staab, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Staab concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction. Dr. Staab measured claimant's ejection fraction to be 62% and stated that "[m]y [ejection fraction] measurement and visual estimation was above 60%."

Based on the auditing cardiologist's finding that claimant did not have a reduced ejection fraction, the Trust issued a post-audit determination denying Ms. Walker's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>4</sup>

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3. (...continued)  
five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is claimant's ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim.

4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit  
(continued...)

In contest, claimant submitted a letter from Keith G. Anderson, M.D., F.A.C.C., in which he stated that he "reviewed the materials provided regarding [Ms. Walker's] claim [and] agree[d] with the attesting cardiologist that the left ventricular ejection fraction is 55%."

The Trust then issued a final post-audit determination, again denying Ms. Walker's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Walker's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5243 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 4, 2005, and claimant submitted a sur-reply on September 13, 2005. Under the Audit Rules, it is within the Special Master's discretion to

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4. (...continued)  
after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Walker's claim.

appoint a Technical Advisor<sup>5</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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5. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Walker argues that there is a reasonable medical basis for her claim because both Dr. Gubin and Dr. Anderson determined that her ejection fraction was reduced. Claimant also contends that, given the subjective nature of measuring an ejection fraction and the fact that Dr. Staab's opinion is based on "visual estimation", there is a reasonable medical basis for the attesting physician's original finding.

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim, and that visual estimation is a well-accepted method of assessing the ejection fraction. The Trust also contends that Dr. Gubin's findings are inconsistent with claimant's echocardiogram report, which states that claimant had "[n]ormal left ventricular size and systolic function; no regional wall motion abnormalities." In addition, the Trust notes that Dr. Anderson did not indicate his method of measurement, whether he actually measured the ejection fraction, or where on the echocardiogram tape he purportedly measured claimant's ejection fraction. Finally, the Trust asserts that Dr. Anderson's letter submitted with claimant's contest is improper because it was not verified in accordance with the Audit Rules.

In her sur-reply, claimant submits an affidavit from Dr. Anderson. In his affidavit, Dr. Anderson reaffirmed his finding that claimant's ejection fraction was 55%. Dr. Anderson also stated that he performed his own measurements in determining

that there was a reasonable medical basis to support Dr. Gubin's findings.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had a reduced ejection fraction. Specifically, Dr. Vigilante stated that:

The left ventricle was normal in size with normal internal dimensions. The left ventricle was not dilated. There was excellent contractility of all walls without regional wall motion abnormalities. Not only was normal wall motion noted but there was hyperdynamic contractility of the left ventricle.... I measured the left ventricular end diastolic and end systolic areas and I calculated the left ventricular ejection fraction via Simpson's Rule. The left ventricular ejection fraction was calculated at between 64% and 65% in several representative cardiac cycles. The left ventricular ejection fraction never approached 60% in any cardiac cycle.

Dr. Vigilante further stated that "[a]n echocardiographer could not reasonably conclude that an ejection fraction of 50%-60% was present on this study even taking into account inter-reader variability."

In response to the Technical Advisor Report, claimant argues that Dr. Vigilante improperly failed to account for inter-reader variability in concluding that there was no reasonable medical basis to support Dr. Gubin's finding of a reduced ejection fraction. According to claimant, there can be inter-reader variability of +/-5% from reader to reader for a total

variability of 10%. Further, claimant argues that ejection fraction measurements are subjective, and that Dr. Vigilante merely substituted his own opinion for that of the attesting physician.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Claimant does not contest the conclusions of the auditing cardiologist or the Technical Advisor that her ejection fraction measured 62% and 64%, respectively. Instead, she argues that there is a reasonable medical basis for her attesting physician's representation because the concept of inter-reader variability allows for differences of "as much as +/-5% from reader to reader for a total variability of 10%." The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement.<sup>6</sup> Adopting claimant's argument regarding inter-reader variability would allow a claimant to recover Matrix Benefits when his or her ejection fraction was greater than 60%, which is the threshold established in the Settlement Agreement. This result would render meaningless the standards established in the Settlement Agreement.

Moreover, contrary to claimant's argument, the Technical Advisor considered inter-reader variability when

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6. For this reason as well, we reject claimant's argument that a "margin of error" in the measurements provides a reasonable medical basis for her claim. See also PTO No. 7110 at 10 (Apr. 12, 2007).



evaluating claimant's ejection fraction. Specifically, Dr. Vigilante stated: "An echocardiographer could not reasonably conclude that an ejection fraction of 50%-60% was present on this study even taking into account inter-reader variability." Thus, Dr. Vigilante did not substitute his opinion for that of the attesting physician. He properly applied the standards set forth in the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Walker's claim for Matrix Benefits.